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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/824,194

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EXAMINER

BASKAR, PADMAVATHI

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 11/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

14

Office Action Summary	Application No. 10/824,194	Applicant(s) MCLEOD ET AL.	
	Examiner Padmavathi v. Baskar	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/27/04.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I Claims 1-3, drawn to a pharmaceutical composition /immunogenic composition comprising Chorismate knocked out parasite *T.gondii*, classified in class 424, subclass 184.1
 - II Claims 4, 11 and 12 drawn to an immunogenic composition comprising cDNA molecule of *T.gondii* cDNA encoding complementary mRNA, classified in class 514 subclass 44 Further election of figure or SEQ.ID.NO is required
 - III Claim 5 drawn to an assay for a candidate inhibitor of *T.gondii*, classified in class 435, subclass 7.9.
 - IV Claims 6 and 7 drawn to a method for detecting life stage of *T.gondii* comprising determining the amount of Chorismate synthase present in sample, classified in class 435, subclass 7.22.
 - V Claims 8, 13 and 15 drawn to genomic DNA, host cell classified in class 536, 435 subclass 23.1, 69.1 respectively. Further election of SEQ.ID.NO or figure or GeneBank Accession Number is required
 - VI Claim 9, drawn to an antibody, classified in class 530, subclass 387.1.
 - VII Claim 10, drawn to a throughput assay, classified in class 435, subclass 7.2.
 - VIII Claim 14, drawn to a method for detecting life stage of *T.gondii* using cDNA molecule, classified in class 536, subclass 24.3
 - IX Claim 16, drawn to a method to inhibit the growth of *T.gondii*, class 530, subclass 300.
2. The inventions are distinct, each from the other because of the following reasons:

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Inventions I is drawn to a composition comprising parasite. Invention V is drawn to polynucleotides, which contain nucleic acids. Inventions VI is drawn to antibody and differs from inventions I and V since antibodies have inherent affinity, avidity and specificity to an antigen that DNA or organism or cDNA is not capable of expressing. Invention II is drawn to another composition comprising cDNA encoding complementary mRNA (antisense), which does not encode any protein and is different from nucleic acid in structure and imparts unique biological structure.

3. Inventions III, IV, VII, VIII and IX are patentably distinct methods which require different biological reagents and parameters for detecting T.gondii or for inhibiting the growth of T.gondii. For example, Invention IX for inhibiting the growth of T.gondii requires plant plastic acetyl -CoA carboxylase and Invention VIII for detecting the life stage of T.gondii requires an amino acid sequence encoded by a cDNA molecule of T.gondii. Invention III is an assay for a candidate inhibitor of T.gondii requires chorismate synthase-green fluorescent reporter protein. Thus these methods are patentably distinct methods utilizing different reagents, steps that result in a different outcome.

4. Invention I/ II/ V/VI and III/IV/ VII/VIII/ IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP. 806.05(h)). In the instant case, the product as claimed can be used in a materially different process of using that product (MPEP. 806.05(h)). For example, the organism can be used in vaccine preparations, nucleotides can be used for amplifying DNA, and antibodies can be used for purifying antigens in immunoaffinity chromatography, the cDNA

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encoding chorismate synthase, said molecule complementary to mRNA can be used to make a double stranded DNA for expressing protein.

5. The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP 821 .04.

Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116., amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

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Further, note that the prohibition against double patenting rejections of 35 U.S.C.121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP 804.01.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.1741).

7. Because these inventions are distinct for the reason given above, have acquired a separate status in the art as shown by their different classification, and while searches may overlap they are not coextensive, restriction for examination purposes as indicated is proper.

8. Applicant is required under 35 U.S.C. 121 to elect a single disclosed SEQ.ID.NO or Figure or GeneBank Accession Number and associated sequence, which share the common structure or overlap the sequence of that SEQ.ID.NO with specific amino acid or nucleic acid from Invention II or V. Applicant is advised that a reply to this requirement must include an identification of the SEQ.ID.NO or Figure or GeneBank Accession Number.

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile

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must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Bruce Campell can be reached on (571) 272-0974. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.


Padma Baskar Ph.D.


MARK NAVARRO
PRIMARY EXAMINER